

REMARKS

Applicant respectfully requests reconsideration. Claims 1-14 were previously pending in this application. Claims 1-14 are canceled herein without prejudice or disclaimer and are replaced with new claims 15-65. Applicant has replaced claims 1-14 with new claims 15-65 to expedite prosecution by introducing new claims written according to U.S. practice, rather than attempting to clarify claims 1-14 according to U.S. practice. As a result, claims 15-65 are now pending for examination with claims 15, 20, 24, 34, 43, 58 and 62 being independent claims. No new matter has been added.

As a result of this amendment, the Examiner's rejections to the canceled claims are rendered moot. However, each of the objection and the rejections made in the Office Action is addressed below as it relates to newly added claims.

Claim Objections

Claim 5 was objected to under 37 CFR § 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim.

Applicant has herein replaced the previous claim set with a new claim set. Claims as amended are written in a proper dependent form. By this amendment, Applicant believes that the Examiner's objection is fully addressed. Withdrawal of the claim objection is respectfully requested.

Rejection Under 35 U.S.C. § 112

Claims 8-10 and 13 were rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In particular, the Examiner argued that essential steps are omitted, rendering these claims indefinite.

Claim 8 relates to method for culturing magnetic cells. As stated above, Applicant has canceled claim 8 without prejudice or disclaimer, thereby rendering this rejection moot. Applicant wishes to point out that newly added claims 20-23 are directed to a culture of magnetic cells, which

are written as product claims, not as method claims. The specification as filed provides an enabling description for a culture of magnetic cells, for example, in Example 1.

Claims 9-10 relate to a method for retaining a magnetic cell and have been herein canceled without prejudice or disclaimer. Applicant has added claims 24-33, which relate to a method for localizing a magnetic cell. The newly added claims include essential steps to practice the claimed method, fully addressing the Examiner's objection provided in the Office Action, page 2. The Examiner additionally pointed out that the phrase "long time" recited in the canceled claim 9 rendered the claim indefinite. In response, Applicant has replaced the expression with "a period of 1-90 days" as recited in claim 29 as currently amended. Support for this recitation is provided on page 15 at line 23 of the specification as filed. By this amendment, Applicant believes that claims 24-33 are definite, and the rejection made under § 112, second paragraph, directed to claims 9-10 is accordingly overcome.

Claims 11-12 have been canceled without prejudice or disclaimer. Claims 34-42 as presented herein relate to a method for controlling a magnetic cell. The newly added claims are supported, for example, on page 3 at lines 18-21, and on page 17 at lines 10-12, of the specification as filed, and provide essential steps to practice the claimed method. Accordingly, the rejection is rendered moot, and the new claims directed to a method for controlling a magnetic cell are definite and enabled.

Claim 13 has been canceled herein without prejudice or disclaimer, making the Examiner's rejection moot.

Based on the foregoing, Applicant submits that the indefinite rejections made under § 112 second paragraph have been fully addressed. Accordingly, withdrawal of the rejections is respectfully requested.

Rejection Under 35 U.S.C. § 102

Claims 1-5 and 8 were rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Margolis et al. (Biochimica et Biophysica Acta. 735: 193-195, 1983).

Claims 1-5 and 8 have been herein canceled without prejudice or disclaimer. Applicant has added new claims 15-19 as product (composition) claims directed to a magnetic cell, with claim 15 being an independent claim.

Claim 15 as presented herein includes the limitation that the peptide has an amino acid sequence comprising RGDS or GRGDS. The Margolis reference does not teach every element of the instant claim, and therefore, the cited reference does not anticipate the instantly claimed invention. Thus, the instant invention is novel over the teaching of Margolis et al. As addressed above in this communication, claim 8 which relates to a method for culturing a magnetic cell has been canceled and replaced with new claims 20-23, drawn to a culture of magnetic cells. Because claims 22-25 incorporate the same limitations recited in claim 15, for the same reason set forth above, Margolis et al. do not anticipate claims 20-23. Accordingly, it is respectfully requested that the rejections made under § 102(b) be reconsidered and withdrawn.

Rejection Under 35 U.S.C. § 103

Claim 6 was rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Margolis et al. in view of Kubo et al. (International Journal of Oncology. 17: 309-315, 2000). Applicant respectfully traverses. As noted above, claim 6 has been canceled, rendering the rejection moot. However, as the subject matter of claim 6 may relate to new claims that recite "a drug," Applicant provides the basis for the traversal below.

Claim 6 is drawn to a magnetic cell according to the invention wherein the magnetic particle further comprises a drug. The rejection asserts that based on the teachings of Margolis et al. and Kubo et al., the claimed invention would have been obvious to one of ordinary skill in the art. Margolis describes a magnetoliposome-based method for sorting fibronectin-expressing embryonic mouse cells *in vitro*. Margolis et al. relates to a method for sorting cells according to their surface antigens. Nothing in the reference teaches a therapeutic composition or a cell linked to a drug-containing component.

Kubo et al. teach magnetic liposomes of about 146 nm in diameter, used as a carrier for an anti-cancer drug. The magnetic cell of the instant claims as amended herein comprises a peptide with an amino acid sequence comprising RDGS or GRGDS which has an adhesive activity for a

molecule on the cell surface. Nothing in the cited references, either alone or in combination, teaches or suggests the instant claims. Therefore, the instantly claimed invention is not obvious over Margolis et al. in view of Kubo et al. Accordingly, it is respectfully requested that the obviousness rejection made under § 103(a) be reconsidered in light of the instant amendment and be withdrawn.

Claim 7 was rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Margolis et al. in view of Bates et al. (The Journal of Biological Chemistry 266(28) 18593-18599, 1991). Applicant has discussed the failings of the Margolis reference above. The Bates reference does not cure those failings.

The Bates reference was cited for the proposition that embryonic fibroblast cells express integrins, and therefore, the mouse embryonic fibroblasts described in Margolis et al. necessarily express integrins, thereby rendering claim 7 obvious. However, Applicant submits that this rejection is rendered moot by the cancellation of claim 7 and by the instant amendment presented herein.

Claims 9-14 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Kubo in view of Margolis. Although the rejection is rendered moot by the cancellation of claims 9-14, Applicant provides the following argument to the extent that the rejection applies to new claims presented herein.

The rejection asserts that the instant invention is obvious over the teachings of Kubo et al. and Margolis et al. because Margolis describes a method for sorting cells according to their surface antigens and Kubo et al. describes magnetoliposome-based delivery of a cancer therapeutic in vivo. Applicant respectfully disagrees with the rejection for the following reasons.

The cell sorting method described in the Margolis reference is drawn to isolating a specific population of cells, i.e., cells expressing fibronectin, amongst a mixture of heterogeneous cell populations, with the use of magnet. The method is particularly useful in a various laboratory contexts where it is desirable to isolate and analyze the specific population of cells. In fact, Margolis et al. does not teach or suggest any clinical application of the cell sorting method. The method described in the Kubo reference does relate to clinical use, for the authors use

magnetoliposomes as a carrier to deliver an anti-cancer drug *in vivo*. However, the magnetoliposome is used merely as a carrier for a therapeutic agent. By contrast, the instant invention concerns a magnetic cell, that *itself* can be used as a therapeutic agent, not merely a carrier thereof. Working examples are provided in specification as filed. Nothing in the Kubo reference teaches or suggests the instant invention, either alone or in combination with the Margolis reference. Applicant believes that the instant claims are distinct from and non-obvious over the cited references. Applicant respectfully request that the Examiner reconsider and withdraw the rejection made under § 103(a).

Based on the foregoing, Applicant submits that all of the rejections have been properly addressed and overcome and that the instant claims are in an allowable condition. A favorable response is earnestly solicited.

CONCLUSION

A Notice of Allowance is respectfully requested. The Examiner is requested to call the undersigned at the telephone number listed below if this communication does not place the case in condition for allowance.

If this response is not considered timely filed and if a request for an extension of time is otherwise absent, Applicant hereby requests any necessary extension of time. If there is a fee occasioned by this response, including an extension fee, the Director is hereby authorized to charge any deficiency or credit any overpayment in the fees filed, asserted to be filed or which should have been filed herewith to our Deposit Account No. 23/2825, under Docket No. T0509.70012US00.

Dated: September 15, 2009

Respectfully submitted,

By 

Michael T. Siekman

Registration No.: 36,276

WOLF, GREENFIELD & SACKS, P.C.

Federal Reserve Plaza

600 Atlantic Avenue

Boston, Massachusetts 02210-2206

617.646.8000